

time the ISFSI or MRS is permanently decommissioned.

Subpart G—Quality Assurance

SOURCE: 64 FR 56122, Oct. 15, 1999, unless otherwise noted.

§ 72.140 Quality assurance requirements.

(a) *Purpose.* This subpart describes quality assurance requirements that apply to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification of structures, systems, and components, and decommissioning that are important to safety. As used in this subpart, “quality assurance” comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. The certificate holder and applicant for a CoC are responsible for the quality assurance requirements as they apply to the design, fabrication, and testing of a spent fuel storage cask until possession of the spent fuel storage cask is transferred to the licensee. The licensee and the certificate holder are also simultaneously responsible for these quality assurance requirements through the oversight of contractors and subcontractors.

(b) *Establishment of program.* Each licensee, applicant for a license, certificate holder, applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this subpart, and satisfying any specific provisions which are applicable to the licensee’s, applicant’s for a license, certificate holder’s, and applicant’s for a CoC activities. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirements’ importance to safety. The qual-

ity assurance program must cover the activities identified in this subpart throughout the life of the activity. For licensees, this includes activities from the site selection through decommissioning prior to termination of the license. For certificate holders, this includes activities from development of the spent fuel storage cask design through termination of the CoC.

(c) *Approval of program.* (1) Each licensee, applicant for a license, certificate holder, or applicant for a CoC shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, in accordance with § 72.4.

(2) Each licensee shall obtain Commission approval of its quality assurance program prior to receipt of spent fuel and/or reactor-related GTCC waste at the ISFSI or spent fuel, high-level radioactive waste, and/or reactor-related GTCC waste at the MRS. Each licensee or applicant for a specific license shall obtain Commission approval of its quality assurance program before commencing fabrication or testing of a spent fuel storage cask.

(3) Each certificate holder or applicant for a CoC shall obtain Commission approval of its quality assurance program before commencing fabrication or testing of a spent fuel storage cask.

(d) *Previously-approved programs.* A quality assurance program previously approved by the Commission as satisfying the requirements of Appendix B to part 50 of this chapter, subpart H to part 71 of this chapter, or subpart G to this part will be accepted as satisfying the requirements of paragraph (b) of this section, except that a licensee, applicant for a license, certificate holder, and applicant for a CoC who is using an Appendix B or subpart H quality assurance program shall also meet the recordkeeping requirements of § 72.174. In filing the description of the quality assurance program required by paragraph (c) of this section, each licensee, applicant for a license, certificate holder, and applicant for a CoC shall notify the NRC, in accordance with § 72.4, of its intent to apply its previously-approved quality assurance program to ISFSI activities or spent fuel storage cask activities. The notification shall identify

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the previously-approved quality assurance program by date of submittal to the Commission, docket number, and date of Commission approval.

[53 FR 31658, Aug. 19, 1988, as amended at 65 FR 50617, Aug. 21, 2000; 66 FR 51843, Oct. 11, 2001]

§ 72.142 Quality assurance organization.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee and certificate holder may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, but the licensee and the certificate holder shall retain responsibility for the program. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall clearly establish and delineate in writing the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components which are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are—

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

(c) The persons and organizations performing quality assurance functions shall report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule considerations when these considerations are opposed to safety

considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

§ 72.144 Quality assurance program.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this subpart. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with these procedures throughout the period during which the ISFSI or MRS is licensed or the spent fuel storage cask is certified. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall identify the structures, systems, and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC, through their quality assurance program(s), shall provide control over activities affecting the quality of the identified structures, systems, and components to an extent commensurate with the importance to safety and, as necessary, to ensure conformance with the approved design of each ISFSI, MRS, or spent fuel storage cask.